NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2698.) The Governor's Office authorized the notice to proceed through the rulemaking process on June 24, 2011.

[R11-203]

PREAMBLE

1. Sections Affected — **Rulemaking Action**
R4-23-411 — Amend

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):
Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. § 32-1974

3. The effective date of the rule:
February 4, 2012

4. Citations to all related notices published in the *Register* to include the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:
Notice of Rulemaking Docket Opening: 17 A.A.R. 1499, August 5, 2011

Notice of Proposed Rulemaking: 17 A.A.R. 1444, August 5, 2011

5. The agency's contact person who can answer questions about the rulemaking:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
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6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:
S.B. 1298 passed by the 50th Legislature changed A.R.S. § 32-1974 to allow pharmacists to administer influenza vaccine to a patient who is at least 6 years of age, but under 18 years of age without a prescription based on approved protocols. S.B. 1298 also allows pharmacists to administer immunizations and vaccines other than influenza to a person who is at least 6 years of age, but under 18 years of age with a prescription order from a medical practitioner based on approved protocols. S.B. 1298 also allows a pharmacy or graduate intern who is certified by the Board to administer immunizations and vaccines under Board rules to do so only in the presence and under the immediate personal supervision of a pharmacist certified by the Board to administer immunizations and vaccines. The rulemaking will amend the language of R4-23-411 (Pharmacist-administered Adult Immunizations) to comply with the requirements of S.B. 1298. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for pharmacist-administered or pharmacy or graduate intern-administered immunizations.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

The proposed rules will impact the Board, pharmacists, pharmacies, and the public. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the proposed rule will have moderate economic impact on pharmacists and pharmacies. The rulemaking will allow properly certified pharmacists to administer influenza vaccine to children age 6 to 17 without a prescription order from a medical practitioner and administer any immunization or vaccine to children age 6 to 17 with a prescription order from a medical practitioner. The rulemaking will also allow a Board-certified pharmacy or graduate intern to administer immunizations and vaccines in the presence of and under the immediate personal supervision of a Board-certified pharmacist. This will increase the number of patients a pharmacist may serve and increase the public's access to needed vaccines. Being able to administer vaccines without a prescription will provide pharmacists or pharmacies with opportunity for increased income. The Board estimates that the ability to administer influenza vaccine without a prescription will provide a potential increased income for pharmacies of from 20 to 50 percent.

The proposed rules will have minimal to moderate economic impact on the public. The public will benefit from increased access to immunization services from pharmacists, including reduced time to receive vaccination without the need to obtain a prescription from a medical practitioner. The Board estimates that the public could save from 20 to 30 percent using a pharmacy setting for vaccinations instead of a scheduled doctor's office visit.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for pharmacist-administered or pharmacy or graduate intern-administered immunizations.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

At the request of the Arizona Community Pharmacy Committee, the Board agreed to amend subsection (H) to extend the certificate renewal period to five years instead of biennially. Since the renewal period is changed, the number of continuing education hours required in subsection (H) is also changed to five contact hours or 0.5 continuing education units for the five-year renewal period to maintain the same ratio from the original proposed rulemaking (two contact hours or 0.2 continuing education units of continuing education for a two-year renewal period). The Board believes the change to the renewal period and subsequently the change in the required continuing education hours needed is not a substantial substantive change. The change will: save the agency money in staff time needed to process fewer renewals each year; for interns, allow the renewal period to coincide with the pharmacy intern license duration period thus allowing a pharmacy intern to only need one certification period before licensure as a pharmacist; provide a cost savings in postage for the agency; and save pharmacists time by only having to renew the immunization certificate every five years instead of every two years.

11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:

A public hearing was held September 6, 2011. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking, but requesting that subsection (H) of the rule be amended to extend the certificate renewal period to every five years instead of biennially. This renewal period would coincide with the pharmacy intern license duration period to allow a pharmacy intern to only need one certification period before licensure as a pharmacist. The change in renewal period will decrease the agency's employee costs by reducing workload and provide a cost savings in postage for the agency, since this certification was not funded by the legislature. The change will also save pharmacists time by only requiring a renewal of the immunization certificate every five years instead of every two years. No other comments were received.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rule itself does not require a permit. However, the certification required by statute arguably falls within the definition of general permit in A.R.S. § 41-1001.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:
No

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:
No

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:
None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:
No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-411. Pharmacist-administered ~~Adult~~ or Pharmacy or Graduate Intern-administered Immunizations

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Pharmacist-administered ~~Adult~~ or Pharmacy or Graduate Intern-administered Immunizations

A. ~~Authority~~ Certification to administer immunizations, vaccines, and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient. As used in this Section, "eligible adult patient" means an eligible patient 18 years of age or older and "eligible minor patient" means an eligible patient at least 6 years of age but under 18 years of age. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, without a prescription, immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section~~;~~.
2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection ~~(C)~~ (D)~~;~~.
3. ~~The~~ For an eligible adult patient, the immunization or vaccine is listed in the United States Centers for Disease Control and Prevention's Recommended Adult Immunization Schedule; or the immunization or vaccine is recommended in the United States Centers for Disease Control and Prevention's Health Information for International Travel~~; and~~.
4. ~~The~~ For an eligible adult patient, the immunization or vaccine is not on the Arizona Department of Health Services list specified in A.A.C. R9-6-1301 as required under A.R.S. § 32-1974 and subsection ~~(H)~~ (I).
5. For an eligible minor patient, the immunization or vaccine is for influenza.
6. For an eligible minor patient, any immunizations or vaccines other than influenza are administered in response to a public health emergency declared by the Governor under A.R.S. § 36-787.

B. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, with a prescription, any immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section.
2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection (D).

~~**B.**~~**C.** A pharmacist or pharmacy or graduate intern who ~~has authority~~ is certified to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall ~~not~~:

1. Not delegate the authority to any other pharmacist, pharmacy or graduate intern, or employee; and
2. Maintain their current certificate for inspection by the Board or its designee or review by the public.

~~**C.**~~**D.** Qualifications for ~~authorization~~ certification to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient. After receipt of a completed application form, the Board shall issue a certificate authorizing the administration of immunizations or vaccines and, in an emergency, epi-

nephrine and diphenhydramine to an eligible adult patient or eligible minor patient to a pharmacist or pharmacy or graduate intern who meets the following qualifications:

1. Has a current~~, unrestricted~~ license to practice pharmacy in this state~~;~~.
2. Successfully completes a training program specified in subsection ~~(D);~~ (E), and
3. Has a current certificate in basic cardiopulmonary resuscitation.

~~D.~~E. ~~Pharmacist-administered adult immunizations~~ Immunizations training program requirements. A training program for pharmacists or pharmacy or graduate interns to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall include the following courses of study:

1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, including administering epinephrine and diphenhydramine to counteract the adverse effects of an immunization given based on a patient-specific prescription order received before administering the immunization;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection ~~(E)~~ (F).

~~E.~~F. Recordkeeping and reporting requirements.

1. A pharmacist or pharmacy or graduate intern granted ~~authorization~~ certification under this Section to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible patient shall provide to the pharmacy the following information and documentation regarding each immunization or vaccine administered:
   a. The name, address, and date of birth of the patient;
   b. The date of administration and site of injection;
   c. The name, dose, manufacturer's lot number, and expiration date of the vaccine, epinephrine, or diphenhydramine;
   d. The name and address of the patient's primary ~~health~~ care provider or physician, as identified by the patient;
   e. The name of the pharmacist or pharmacy or graduate intern administering the immunization;
   f. A record of the pharmacist's or pharmacy or graduate intern's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
   g. The date and time that the written report specified in subsection ~~(E)(2)~~ (F)(2) was sent to the patient's primary ~~health~~ care provider or physician;
   h. Consultation or other professional information provided to the patient by the pharmacist or pharmacy or graduate intern; ~~and~~
   i. The name and date of the vaccine information sheet provided to the patient; and
   j. For immunizations or vaccines given to an eligible minor patient, a consent form signed by the minor's parent or guardian.
2. The pharmacist or pharmacy or graduate intern shall provide a written report to the patient's primary ~~health~~ care provider or physician containing the documentation required in subsection ~~(E)(1)~~ (F)(1) within 48 hours after the immunization. The pharmacy shall make the required records specified in subsection ~~(E)(1)~~ (F)(1) and a record of compliance with this subsection available in the pharmacy for inspection by the Board or its designee.
3. A pharmacy's pharmacist-in-charge shall maintain the records required in subsection ~~(E)(1)~~ (F)(1) in the pharmacy for a minimum of seven years from the immunization's administration date.

~~F.~~G. Confidentiality of records. A pharmacist, pharmacy or graduate intern, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.

~~G.~~H. Renewal of a certificate for pharmacist-administered ~~adult~~ immunizations. A certificate authorizing a pharmacist to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall be renewed ~~biennially~~ every five years by submitting a renewal request within the 30 days before the certificate's expiration date. A pharmacist desiring to renew the certificate shall provide to the Board proof of the following:

1. Current certification in basic cardiopulmonary resuscitation, and
2. Completion of a minimum of ~~two~~ five contact hours (~~0.2~~ 0.5 CEU) of continuing education related to immunizations during the five-year renewal period. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

~~H.~~I. Pharmacist-administered or pharmacy or graduate intern-administered adult immunizations that require a prescription order. A pharmacist or pharmacy or graduate intern certified by the Board to administer adult immunizations or vaccines shall not administer any immunization or vaccine listed in A.A.C. R9-6-1301 without a prescription order. In addition to filing a prescription order as required in A.R.S. § 32-1964, a pharmacist or pharmacy or graduate intern who administers an immunization or vaccine listed in A.A.C. R9-6-1301 shall comply with the recordkeeping requirements of subsection ~~(E)(1)~~ (F)(1).

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2698.) The Governor's Office authorized the notice to proceed through the rulemaking process on June 24, 2011.

[R11-202]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-421	Repeal
R4-23-422	Repeal
R4-23-423	Repeal
R4-23-424	Repeal
R4-23-425	Repeal
R4-23-426	Repeal
R4-23-427	Repeal
R4-23-428	Repeal
R4-23-429	Repeal

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. § 32-1970

3. The effective date of the rule:

February 4, 2012

4. Citations to all related notices published in the *Register* to include the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 17 A.A.R. 1500, August 5, 2011

Notice of Proposed Rulemaking: 17 A.A.R. 1447, August 5, 2011

5. The agency's contact person who can answer questions about the rulemaking:

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1700 W. Washington St., Suite 250
Phoenix, AZ 85007

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Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

S.B. 1298 passed by the 50th Legislature changed A.R.S. § 32-1970 to allow a pharmacist to enter into a protocol-based drug therapy agreement with a provider to implement, monitor, or modify the drug therapy of a patient of the provider. The changes remove the requirement that drug therapy management must occur in a particular practice setting.

Because the statutory language has everything needed for a pharmacist to enter into a protocol-based drug therapy agreement with a provider, we do not need the existing rules for drug therapy management in R4-23-421 through R4-23-429. The rulemaking will repeal the drug therapy management rules in R4-23-421 Drug Therapy Management, R4-23-422 Drug Therapy Management - Duties of the Board, R4-23-423 Drug Therapy Management Advisory Committee, R4-23-424 Drug Therapy Management - Pharmacist and Physician Qualifications, R4-23-425 Drug Therapy Management - Pharmacist Duties, R4-23-426 Drug Therapy Management - Physician Duties, R4-23-427 Drug Therapy Management - Documentation, R4-23-428 Drug Therapy Management - Quality Assurance, and R4-23-429 Drug Therapy Management - Privacy.

The Board believes that repeal of these rules will benefit the public health and safety by reducing the rules burden and allowing the statutory standards to be used to clearly establish the standards for drug therapy management by pharmacists.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

The proposed rules will impact the Board, pharmacists, pharmacies, and the public. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The drug therapy management rules were put in place November 9, 2002. Since that time only five pharmacists have received approval to perform drug therapy management. The previous statute and rules were very restrictive and only allowed drug therapy management to occur in hospitals, long-term care facilities, community health care centers, and health maintenance organization pharmacies. The process to get and maintain an agreement was very cumbersome. The Arizona Pharmacy Alliance worked with the health care providers to agree on a statute that allows drug therapy management to occur in any pharmacy practice setting. The statute requires an agreement between the provider, pharmacist, and patient based on written protocols for a pharmacist to implement, monitor, or modify the patient's drug therapy. Because of the way the statute was written, all the language prescribing the requirements for a pharmacist to enter into an agreement with a provider and perform drug therapy management under that provider's supervision, including necessary definitions, is in the statute, so we no longer need the existing rules. The rulemaking will repeal nine unnecessary Sections of rules.

The Board estimates the rulemaking will have a no impact on pharmacists and pharmacies.

The Board believes that repeal of these rules will benefit the public health and safety by reducing the rules burden and allowing the statutory standards to be used to clearly establish the standards for drug therapy management by pharmacists.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

There are no substantial changes in the final rules from the proposed rules.

11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:

A public hearing was held September 6, 2011. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

No

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

No

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-421. ~~Drug Therapy Management~~ Repealed
R4-23-422. ~~Drug Therapy Management - Duties of the Board~~ Repealed
R4-23-423. ~~Drug Therapy Management Advisory Committee~~ Repealed
R4-23-424. ~~Drug Therapy Management - Pharmacist and Physician Qualifications~~ Repealed
R4-23-425. ~~Drug Therapy Management - Pharmacist Duties~~ Repealed
R4-23-426. ~~Drug Therapy Management - Physician Duties~~ Repealed
R4-23-427. ~~Drug Therapy Management - Documentation~~ Repealed
R4-23-428. ~~Drug Therapy Management - Quality Assurance~~ Repealed
R4-23-429. ~~Drug Therapy Management - Privacy~~ Repealed

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-421. ~~Drug Therapy Management~~ Repealed

~~**A.** A pharmacist qualified under R4-23-424 may provide drug therapy management under A.R.S. § 32-1970 after a physician's initial diagnosis of a patient if drug therapy management:~~
~~1. Is guided by a Board-approved drug therapy management agreement; and~~
~~2. Occurs in one of the following pharmacy practice sites:~~
~~a. An acute care hospital,~~
~~b. A nursing care institution,~~
~~c. A staff model HMO, or~~
~~d. A community health center as defined in A.R.S. § 32-1921 and A.R.S. § 36-2907.06.~~

~~**B.** A drug therapy management agreement shall contain the following:~~
~~1. The criteria and medical conditions under which the pharmacist may modify a patient's drug therapy;~~
~~2. The specific modifications of drug therapy that the pharmacist may make including drug, dose, and dosage form;~~
~~3. The criteria and medical conditions under which the pharmacist may implement a patient's drug therapy;~~
~~4. The specific drug therapy that a pharmacist may implement including drug, dose, and dosage form;~~
~~5. The subjective and objective patient assessment parameters that a pharmacist uses to evaluate a patient's drug therapy at each patient visit, including ordering and interpreting a patient's laboratory tests;~~
~~6. The subjective and objective patient assessment criteria that indicate when a pharmacist shall consult with a supervisory physician or if unavailable, an alternate physician, including the timing and nature of a consultation with or referral to a supervisory or alternate physician and the specific procedures for a consultation with or referral to a supervisory or alternate physician;~~
~~7. The content and frequency of the periodic status report on a patient that a pharmacist shall provide in writing to or in a meeting with the supervisory physician;~~
~~8. The procedure for terminating the drug therapy management agreement;~~
~~9. The names of the supervisory physician, the alternate physician, and the pharmacist authorized to provide services under the agreement; and~~
~~10. The signature of all persons named in subsection (B)(9).~~

R4-23-422. ~~Drug Therapy Management - Duties of the Board~~ Repealed

~~**A.** The Board shall:~~
~~1. Appoint a Drug Therapy Management Advisory Committee;~~
~~2. In consultation with Board staff and the Drug Therapy Management Advisory Committee, approve or deny an initial drug therapy management agreement and the annual renewal of an existing drug therapy management agreement;~~
~~3. Terminate a pharmacist's drug therapy management agreement if the pharmacist:~~
~~a. Does not renew the agreement on or before the approval date anniversary; or~~
~~b. Is found by the Board to lack the qualifications required in R4-23-424; and~~
~~4. In processing a drug therapy management agreement application, comply with the application process established in R4-23-602, except the substantive review time-frame is 180 days and the overall time-frame is 200 days.~~

~~**B.** The Board may terminate a pharmacist's drug therapy management agreement if the Board determines that the pharmacist is violating the requirements of the drug therapy management agreement or federal or state drug laws.~~

R4-23-423. ~~Drug Therapy Management Advisory Committee~~ Repealed

~~A.~~ ~~The Drug Therapy Management Advisory Committee shall:~~
~~1. Consist of an osteopathic physician, an allopathic physician, and two pharmacists with prior or current experience in drug therapy management;~~
~~2. Serve at the pleasure of the Board;~~
~~3. Serve for a term of two years unless removed or reappointed by the Board;~~
~~4. Review initial and renewal drug therapy management agreement applications; and~~
~~5. Advise the Board regarding the approval or denial of reviewed drug therapy management agreement applications.~~
~~B.~~ ~~The Drug Therapy Management Advisory Committee members are not eligible for compensation from the Board.~~

R4-23-424. ~~Drug Therapy Management - Pharmacist and Physician Qualifications~~ Repealed

~~A.~~ ~~Pharmacist qualifications.~~
~~1. Before initiating a drug therapy management agreement with a supervisory physician, a pharmacist shall have:~~
~~a. A current, unrestricted license issued by the Board; and~~
~~b. Proof of one of the following:~~
~~i. Completion of a pharmacy practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association;~~
~~ii. Current board specialty certification from the Board of Pharmaceutical Specialists or current certification as a Certified Geriatric Pharmacist;~~
~~iii. A Doctor of Pharmacy degree and completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement; or~~
~~iv. A Bachelor's degree in Pharmacy, satisfactory completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement, and appropriate credentialing issued by the governing body of a qualifying Arizona practice site described in A.R.S. § 32-1970.~~
~~2. To ensure that a pharmacist who provides drug therapy management is competent to continue providing the services delineated in a drug therapy management agreement, a pharmacist shall annually complete six contact hours (0.6 CEU's) of continuing education for each area of practice covered by the pharmacist's drug therapy management agreement. The continuing education hours may be used to satisfy the continuing education requirements for licensure as a pharmacist.~~
~~B.~~ ~~Supervisory physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, a supervisory physician shall:~~
~~1. Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and~~
~~2. Not be a resident in a post-graduate medical training program.~~
~~C.~~ ~~Alternate physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, an alternate physician shall:~~
~~1. Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and~~
~~2. Not be a resident in a post-graduate medical training program.~~

R4-23-425. ~~Drug Therapy Management - Pharmacist Duties~~ Repealed

~~A.~~ ~~To obtain initial approval for a drug therapy management agreement, a pharmacist shall submit a completed application, on a form furnished by the Board, that includes:~~
~~1. Pharmacist name and Arizona pharmacist license number;~~
~~2. Documentation of the pharmacist's qualifications as specified in R4-23-424;~~
~~3. Practice site name, address, mailing address if different, telephone number, and fax number;~~
~~4. Documentation of practice site qualification under A.R.S. § 32-1970;~~
~~5. Supervisory physician name, office address, mailing address if different, telephone number, and fax number;~~
~~6. Documentation of the supervisory physician's qualifications as specified in R4-23-424;~~
~~7. Alternate physician name, office address, mailing address if different, telephone number, and fax number;~~
~~8. Documentation of the alternate physician's qualifications as specified in R4-23-424;~~
~~9. Description of the pharmacist's practice area or areas for which approval is sought;~~
~~10. An original and 11 copies of the drug therapy management agreement covering each practice area for which Board approval is sought;~~
~~11. Dated and signed affirmation of the supervisory physician's acceptance of the responsibility for oversight of the pharmacist's drug therapy management;~~
~~12. Dated and signed affirmation of an alternate physician's acceptance of the responsibility for temporary oversight of the pharmacist's drug therapy management; and~~
~~13. Dated and signed affirmation of the pharmacist's acceptance of the responsibility to provide drug therapy manage-~~

ment as described in the drug therapy management agreement.

B. To renew an existing drug therapy management agreement, a pharmacist shall submit a completed renewal application, on a form furnished by the Board, that includes, in addition to the requirements of subsection (A), the following:

1. Documentation that the supervisory physician, alternate physician, and participating pharmacist reviewed the protocols contained in the agreement;
2. Documentation that the participating pharmacist completed the continuing education requirements specified in R4-23-424; and
3. An original and 11 copies of the drug therapy management agreement covering each practice area for which renewal is sought, including highlighting any requested modifications to the agreement.

C. A pharmacist who participates in a Board-approved drug therapy management agreement shall:

1. Renew the agreement annually on or before the initial approval date anniversary;
2. Before submitting the application to renew the agreement, participate with the supervisory physician in reviewing the agreement;
3. Notify the Board within ten days of termination of the drug therapy management agreement;
4. During the first appointment with a patient under a Board-approved drug therapy management agreement:
   a. Verify that a copy of the drug therapy management agreement, which includes the signature of the supervisory physician, alternate physician, and pharmacist, is placed in the patient's medical record;
   b. Verify that a copy of the supervisory physician's written order, which authorizes the pharmacist to collaboratively manage the patient's drug therapy, is placed in the patient's medical record; and
   c. Verify that a copy of the patient's written consent, which shows that the patient understands the pharmacist's role in the patient's care, the nature of the relationship with the supervisory physician, and the procedure for revoking consent, is placed in the patient's medical record;
5. Ensure compliance with the documentation requirements of R4-23-427;
6. Ensure compliance with quality assurance program required in R4-23-428;
7. Ensure compliance with the privacy requirements of R4-23-429; and
8. Comply with the Board-approved drug therapy management agreement.

R4-23-426. ~~Drug Therapy Management – Physician Duties~~ Repealed

A. Before referring a patient to a pharmacist, a supervisory physician who participates in a Board-approved drug therapy management agreement shall:

1. Have a physician-patient relationship with the patient and make a diagnosis of the patient;
2. Review the approved drug therapy management agreement with the patient;
3. Obtain the patient's consent to participate in the drug therapy management agreement;
4. Document the patient's consent to participate in the drug therapy management agreement by obtaining the patient's dated and signed consent that states that the patient has read, understood, and agreed to participate in the drug therapy management agreement. The dated and signed consent shall be placed in the patient's medical records;
5. Authorize a specific pharmacist to collaboratively manage a patient's drug therapy by placing a written order in the patient's medical record; and
6. Place a copy of the approved drug therapy management agreement in the patient's medical record to provide notice to other health care providers of the drug therapy management.

B. Physician supervision. A supervisory physician who supervises a pharmacist under a Board-approved drug therapy management agreement shall:

1. Before submitting the application to renew the agreement and in consultation with the participating alternate physician and pharmacist, review and approve the drug therapy management agreement;
2. Review and initial the pharmacist's documented care for appropriateness of care and compliance with the drug therapy management agreement when the patient visits the supervisory physician for follow-up or any other services;
3. Routinely evaluate the patient care provided by the pharmacist as specified in the drug therapy management agreement; and
4. Ensure that the supervisory physician or the alternate physician is readily available to the pharmacist for consultation, assistance, and direction by direct telecommunication or physical presence at the practice site.

C. Alternate physician duties. An alternate physician who participates in a Board-approved drug therapy management agreement shall ensure that the alternate physician is available to:

1. Temporarily assume responsibility for supervision and evaluation of the drug therapy management performed by the pharmacist;
2. Provide consultation, assistance, and direction to the pharmacist when the supervisory physician is unavailable; and
3. Before submitting the application to renew the agreement, participate with the supervisory physician and pharmacist in reviewing the agreement.

R4-23-427. ~~Drug Therapy Management – Documentation~~ Repealed

~~Documenting pharmacist-provided drug therapy management. A pharmacist who participates in drug therapy management~~

~~under a Board-approved drug therapy management agreement shall:~~

~~1. After each patient-pharmacist appointment, document the drug therapy management for the patient in the patient's medical record at the practice site, including patient data, assessment of patient status, and treatment plan;~~
~~2. Date and sign the documentation required in subsection (1) in a patient's medical record with the pharmacist's first and last name, title, and Arizona pharmacist license number;~~
~~3. Document a consultation with or referral to the supervisory physician or the alternate physician; and~~
~~4. Document a consultation with a supervisory or alternate physician that results in a pharmacist's need to generate the physician's verbal prescription order for a drug not included in the drug therapy management agreement. The documentation shall include:~~
~~a. The phrase "verbal order by Dr." and the name of the supervisory physician or alternate physician authorizing the verbal prescription order,~~
~~b. The date and signature of the pharmacist generating the verbal prescription order in the same manner described in subsection (2), and~~
~~c. The countersignature of the supervisory physician or alternate physician authorizing the verbal prescription order within 72 hours of the pharmacist-generated verbal prescription order.~~

R4-23-428. ~~Drug Therapy Management - Quality Assurance~~ Repealed

~~**A.** A pharmacist who provides drug therapy management shall, in cooperation with the supervisory physician and the appropriate committee of the practice site, develop and implement a continuous quality assurance and improvement program that includes standards and procedures to identify, evaluate, and improve the quality of pharmacist-provided drug therapy management.~~
~~**B.** Periodic status reports or meetings between a pharmacist and supervisory physician regarding care of a patient under the drug therapy management agreement shall include evaluating and documenting patient status and the quality of care provided by the pharmacist.~~

R4-23-429. ~~Drug Therapy Management - Privacy~~ Repealed

~~**A.** A pharmacist who provides drug therapy management shall perform drug therapy management activities in a private and distinct area of the practice site.~~
~~**B.** In a practice site where a pharmacist provides drug therapy management under a drug therapy management agreement, a pharmacy permittee shall ensure that a private and distinct area of similar size and environment to that used by other primary care providers at the practice site is available for the performance of pharmacist-provided drug therapy management activities.~~

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 46. BOARD OF APPRAISAL

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2698.) The Governor's Office authorized the notice to proceed through the rulemaking process on May 24, 2011.

[R11-201]

PREAMBLE

1. Sections Affected | **Rulemaking Action**
R4-46-106 | Amend

2. Citations to the agency's statutory rulemaking authority to include both the authorization statue and the implementing statute:

Authorizing statute: A.R.S. § 32-3607(A)(6)

Implementing statute: A.R.S. § 32-3607(A)(6)

3. The effective date of the rules:

December 6, 2011

An immediate effective date is requested under A.R.S. § 41-1032(A)(2) because the rule helps avoid a violation of federal law and there has not been agency delay or inaction. Federal law increased the fee for state appraisers from $25 annually to $40 annually and this rulemaking amends the Board's rules to reflect this. The Appraisal Subcommittee requires state agencies to start collecting the increased National Registry fee effective January 1, 2012. The Gov-

ernor's approval for an exception to the rules moratorium was requested on April 25, 2011 and approval was received on May 24, 2011. The Notice of Rulemaking Docket Opening was filed on June 23, 2011 and Board staff completed the Notice of Proposed Rulemaking as quickly as possible and submitted it to the Secretary of State on July 18, 2011.

4. Citations to all related notices published in the *Register* to include the *Register* as specified in R1-1-409 (A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 17 A.A.C. 1301, July 15, 2011

Notice of Proposed Rulemaking: 17 A.A.C. 1384, July 29, 2011

5. The agency's contact person who can answer questions about the rulemaking:

Name: Daniel Pietropaulo

Address: 1400 W. Washington St., Suite 360
Phoenix, AZ 85007

Telephone: (602) 542-1566

Fax: (602) 542-1598

E-mail: daniel.pietropaulo@appraisal.state.az.us

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered to include and explanation about the rulemaking:

At its May 2011 meeting the Board voted to open a docket regarding the Appraisal Subcommittee fee increase. The Appraisal Subcommittee (ASC) is established by Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). In accordance with section 1109 of Title XI (12 U.S.C. 3338), the ASC shall have the authority to receive an annual fee from each state licensed or certified appraiser eligible to do appraisals federally related transactions of not more than $40 for the purpose of maintaining a national database of license and certified appraisers. The fee may be modified up to a maximum of $80 per annum in accordance with section 1109 (a)(4)(A) of Title XI. The Board proposes to amend the current rule to conform to the Appraisal Subcommittee's modification of the annual national registry fee. This proposed change to the rule is in reference to the ASC Bulletin 10-1 as of October 14, 2010, published by the Appraisal Subcommittee, which will become effective on January 1, 2012.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

The Appraisal Subcommittee is raising the annual national registry fee from $25 to $40 annually, effective January 1, 2012. The financial impact to small businesses, appraisers, and consumers is minimal as the fee increase for the appraiser is $15 per year or $30 on a biennial basis.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

None

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

No comments or requests for oral proceedings were received during the public comment period after the Notice of Proposed Rulemaking was posted by the Secretary of State.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to an specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

This rule does not require a permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Federal law is applicable to the subject matter of the rule and the rule is not more stringent than federal law. The Board proposes to amend the current rule to conform to the Appraisal Subcommittee's modification of the annual

national registry fee. This proposed change to the rule is in reference to the ASC Bulletin 10-1 as of October 14, 2010, published by the Appraisal Subcommittee, which will become effective on January 1, 2012.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis was submitted to the agency.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

This rule was not previously made, amended or repealed as an emergency rule.

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 46. BOARD OF APPRAISAL

ARTICLE 1. GENERAL PROVISIONS

Section
R4-46-106. Fees

ARTICLE 1. GENERAL PROVISIONS

R4-46-106. Fees

A. No change
1. No change
2. No change
3. No change
4. No change
5. Biennial National Registry: ~~$50~~ $80
6. No change
7. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
   b. No change
      i. No change
      ii. No change
      iii. No change

B. No change
C. No change

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 8. DEPARTMENT OF HEALTH SERVICES
FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2698.) The Governor's Office authorized the notice to proceed through the rulemaking process on July 28, 2011.

[R11-200]

PREAMBLE

1. Articles Parts, or Sections Affected **Rulemaking Action**

R9-8-101	Amend
R9-8-102	Amend

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 36-136(A)(7) and (F)

Implementing statute: A.R.S. § 36-136(H)(4) as amended by Laws 2011, Ch. 84

3. The effective date of the rule:

February 4, 2012

4. Citations to all related notices published in the *Register* to include the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 17 A.A.R. 1639, August 19, 2011

Notice of Proposed Rulemaking: 17 A.A.R. 1606, August 19, 2011

5. The agency's contact person who can answer questions about the rulemaking:

Name:	Diane Eckles, Office Chief
Address:	Department of Health Services Office of Environmental Health 150 N. 18th Ave., Suite 140 Phoenix, AZ 85007
Telephone:	(602) 364-3142
Fax:	(602) 364-3146
E-mail:	Diane.Eckles@azdhs.gov
	or
Name:	Thomas Salow, Manager
Address:	Department of Health Services Office of Administrative Counsel and Rules 1740 W. Adams St., Suite 203 Phoenix, AZ 85007
Telephone:	(602) 542-1020
Fax:	(602) 364-1150
E-mail:	Thomas.Salow@azdhs.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Since the rules in *Arizona Administrative Code* (A.A.C.) Title 9, Chapter 8, Article 1, were last revised, several statutory changes have been made to Arizona Revised Statutes (A.R.S.) § 36-136 that affect these rules. Laws 2006, Ch. 272, § 1 requires the Department to adopt rules that provide an exemption from the requirements in 9 A.A.C. 8, Article 1 for food and drink that is served at a noncommercial social event that takes place at a workplace, is prepared at a cooking school that is conducted in an owner-occupied home, is not potentially hazardous, or is prepared or served at an employee-conducted function that lasts less than four hours and is not regularly scheduled. Laws 2006, Ch. 272,

§ 1 also specifies the conditions under which "a kitchen in a private home that is used as a cooking school and that prepares and offers food to students" is exempt from the requirements in 9 A.A.C. 8, Article 1 until the Department adopts rules providing an exemption. Laws 2008, Ch. 149, § 1 requires the Department to adopt rules that clarify that food and drink that is not potentially hazardous and is prepared in a kitchen of a private home for occasional sale or distribution for noncommercial purposes is not subject to the requirements in 9 A.A.C. 8, Article 1. Laws 2008, Ch. 149, § 1 adds to the food and drink that is to be exempted by rule "commercially prepackaged food that is not potentially hazardous and whole fruits and vegetables that are washed and cut onsite for immediate consumption" offered at a child care facility and "commercially prepackaged food and drink that is not potentially hazardous and that is displayed in an area of less than 10 lineal feet." Laws 2011, Ch. 84, § 1 requires the Department to add baked and confectionary goods "that are not potentially hazardous and that are prepared in a kitchen of a private home for commercial purposes" to the list of food or drink to be exempted by rule from the requirements in 9 A.A.C. 8, Article 1 if specific conditions are met.

The Department received an exception from the Governor's rulemaking moratorium, established by Executive Order 2011-05, and is amending the rules in 9 A.A.C. 8, Article 1, to implement these statutory changes. The amended rules make clear that certain foods, as specified in statute, are exempt from the requirements in 9 A.A.C. 8, Article 1 and, therefore, from inspection by a regulatory authority of a kitchen in which they are prepared or regulation of their production, sale, or consumption by a regulatory authority. However, the Department or county sanitarians may enforce the provisions of A.R.S. §§ 36-601(A)(2), 36-602, and 36-603 if the foods are considered to constitute a public nuisance. The amended rules conform to rulemaking format and style requirements of the Council and the Office of the Secretary of State.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study related to this rulemaking package.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

As used in this summary, annual costs/revenues are designated as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000. Costs are listed as significant when meaningful or important, but not readily subject to quantification. Only the economic, small business, and consumer impact directly attributable to this rulemaking, rather than the impact imposed by the statute or resulting from improved implementation of other rules in the Article is considered.

The Department believes that the amended rules may provide a significant benefit to the Department and county sanitarians by improving the ability of Department and county sanitarians to effectively implement A.R.S. § 36-136(H)(4). The amended rules may cause a minimal-to-moderate decrease in revenue to a county as a result of individuals who prepare not-potentially hazardous baked or confectionary goods that meet the requirements for exemption in statute and rule no longer obtaining unnecessary food establishment permits from the county. By clarifying the applicability of the rules in 9 A.A.C. 8, Article 1, the amended rules may provide a significant benefit to regulated food establishments; persons providing food or drink that is exempt under A.R.S. § 36-136(H)(4)(a), (c), (d), (e), or (f); and individuals who prepare not-potentially hazardous baked or confectionary goods for commercial purposes in a private home. In addition, persons providing food or drink that is exempt under A.R.S. § 36-136(H)(4)(a), (c), (d), (e), or (f) and individuals who prepare not-potentially hazardous baked or confectionary goods for commercial purposes in a private home may receive a minimal-to-substantial benefit from the amended rules through saving the expense of applying for a food establishment license or permit and ensuring compliance of their kitchens with requirements in 9 A.A.C. 8, Article 1.

Persons who prepare baked or confectionary goods in a regulated food establishment may incur a decrease in revenue if potential customers buy home-baked or confectionary goods from unregulated individuals. Persons who rent kitchen space that meets the requirements in 9 A.A.C. 8, Article 1 to persons who prepare baked or confectionary goods may also incur a decrease in revenue if potential customers begin preparing the baked or confectionary goods in the kitchen of a private home. However, these impacts are caused by the statutory change rather than the rules.

Individuals obtaining food or drink affected by the rule change may receive a significant benefit from the requirements in the amended rules that the label on exempt baked or confectionary goods specify that the baked or confectionary goods were prepared in a private home and the listing as exempt of other food or drink. Owners or operators of cooking schools are not considered to be affected by the rulemaking since Laws 2006, Ch. 272, § 1 already provides an exemption from the requirements in 9 A.A.C. 8, Article 1 if specified conditions are met.

The Department has determined that the benefits outweigh any potential costs associated with this rulemaking.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and final rulemaking:

Minor technical and grammatical changes were made by the Department and at the suggestion of staff of the Council and Office of the Secretary of State to improve clarity. These changes include the clarification that foods exempt from 9 A.A.C. 8, Article 1 are not subject to routine inspection by a regulatory authority. Although the Department believes this was understood by readers of the current rule, the Department is choosing to specify it to eliminate any possibility of confusion.

11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:

Seven individuals attended the oral proceeding, and six of these individuals provided oral comments. The Department received written comments from six persons, some of which sent multiple sets of comments and two of which restated oral comments provided during the oral proceeding. All of these comments addressed the exemption of baked or confectionary goods prepared in the kitchen of a private home for commercial purposes. The comments and the Department's responses are given below. For comments made by the same person in different venues/documents, the comment and response is listed only once.

Comment	Department's Response
An individual asked whether the food label is meant to provide the address where the food was prepared or just contact address.	Laws 2011, Ch. 84, § 1 requires the label to contain the address of the "maker" and include "contact information for the maker." Since the person preparing or supervising the preparation of the baked or confectionary goods must be registered with the Department, the Department is requiring that contact information for the registered individual be included on the label to satisfy the statutory requirement. No change will be made to the rule.
Two individuals asked for online verification of registration of an individual as a food preparer who is authorized to prepare food for commercial purposes and of food handler's certificates and one requested that a reference to a business license should be included in the registration process.	Requirements for registration are specified in A.R.S. § 36-136(H)(4)(g), not rule. No change will be made to the rule. The Department will make a list of registered individuals available on the Department's web site.
An individual asked about rules regarding home canned goods and home-made goat cheese.	Canned goods and goat cheese are potentially hazardous, as defined in the Food Code, and must be prepared in a licensed food establishment. Requirements for food establishments are specified elsewhere in 9 A.A.C. 8, Article 1. No change will be made to the rule.
An individual asked that a requirement be added to the rules that a certificate of registration be displayed by a vendor of baked or confectionary goods at a farmer's market, bazaar, etc.	The Department wants to make the regulatory burden on stakeholders as low as possible, while protecting health and safety. A requirement to display the certificate of registration is not included in A.R.S. § 36-136(H)(4)(g), so the requirement is not in 9 A.A.C. 8, Article 1. If the intent had been to require the display of the certificate, the requirement would have been included in the statute as it was for cooking schools in A.R.S. § 36-136(M). However, a county sanitarian enforcing the rules in 9 A.A.C. 8, Article 1 may ask to see the certificate of registration for a vendor selling baked or confectionary goods at such a venue to verify that the foods are exempt. No change will be made to the rule.
An individual asked whether the sponsor of a farmer's market/bazaar should ask to see a certificate or food-handler's card when accepting vendor registrations.	This comment does not address the content of the rule. Whether or not to ask for these documents is up to the sponsor. No change will be made to the rule.
An individual asked who enforces the rule, whether there are penalties for non-compliance, and what should be done if a product does not have a label.	County sanitarians enforce the rules in 9 A.A.C. 8, Article 1, and can impose penalties for non-compliance for foods and food establishments subject to these rules. An individual who sees products without labels may report the violation to a county sanitarian. No change will be made to the rule.

An individual expressed concern about county enforcement of the provision of Laws 2011, Ch. 84, § 1 related to baked and confectionary goods, stating that county sanitarians are preventing regulated food establishments from purchasing baked or confectionary goods from a home-baker and not allowing an individual registered as a food preparer who is authorized to prepare food for commercial purposes to participate in events where their goods will be sold without obtaining a temporary catering permit.	Until the amended rule is effective, county sanitarians may interpret the provisions of the Food Code relating to a regulated food establishment obtaining food only from an approved source to exclude home-bakers from selling their baked or confectionary goods to retail food establishments. County sanitarians may also have been interpreting A.R.S. § 36-136(H)(4)(g) to mean that there is no exemption until the exemption is incorporated into rule and the rule becomes effective. The former concern is addressed by R9-8-102(C), which specifies that the kitchen in a private home in which baked or confectionary goods are prepared that meet the requirements in A.R.S. § 36-136(H)(4)(g) and (H)(13) and this rule is an approved source of baked or confectionary goods. The latter is addressed by R9-8-102(B)(10). No change will be made to the rule.
An individual expressed concern about the registration process, stating that the Department should impose a fee for annual registration as a food preparer who is authorized to prepare food for commercial purposes and collect more information about the household that may affect the safety of the baked or confectionary goods produced. The individual recommended that the Department should be able to approve a menu of goods that a registrant may prepare. Another individual also suggested that the Department collect a registration fee.	This comment does not address the content of the rule but rather addresses the statute, which does not contain a provision for the imposition of a fee, for annual registration, or for approval of a menu of approved baked or confectionary goods. No change will be made to the rule. The Department is considering requesting more information during registration.
Two individuals expressed concern that only a food handler's card is required for an individual preparing exempt baked or confectionary goods, rather than a food manager's card, which is easily obtained but requires an individual to have more knowledge of safe food handling.	This comment does not address the content of the rule but rather addresses the statute. No change will be made to the rule.
Several individuals who own regulated food establishments providing baked goods expressed concern about the safety of in-home baked goods and stated that individuals selling cakes and other baked goods from their homes will put small businesses providing similar items at a great economic disadvantage.	These comments do not address the content of the rule but rather address the statute. The exemption, however, only applies to not-potentially hazardous baked and confectionary goods. Therefore, a regulated food establishment may provide a greater range of baked goods, such as those with cream or pudding fillings, cheese cakes, or butter-cream frostings, that are potentially hazardous, as defined in the Food Code, and cannot be provided from an unregulated kitchen. No change will be made to the rule.
An individual from the Apache County Public Health Service District asked that the terms "confectionary goods," "baked goods," and "commercial" be defined.	The Department is using the dictionary definitions of these terms and does not see a need to define them. No change will be made to the rule.
An individual from the Apache County Public Health Service District asked whether individuals preparing food in their homes for public consumption will be required to have a food worker certificate.	A.R.S. § 36-136(H)(4)(g) requires an individual preparing or supervising the preparation of baked or confectionary goods exempt from 9 A.A.C. 8, Article 1 to obtain a food handler's card if one is issued by the county. R9-8-102(B)(10)(b) has been changed in the final rulemaking to clarify the statutory requirement.
The Apache County Public Health Service District and the Maricopa County Environmental Services Department stated opposition to allowing baked or confectionary goods to be produced in an unregulated kitchen, expressing concern about environmental sources of contamination that may affect the safety of the foods.	This comment does not address the content of the rule but rather addresses the statute, which exempts not-potentially hazardous baked or confectionary goods from the requirements of 9 A.A.C. 8, Article 1 under specific conditions. No change will be made to the rule.

The Apache County Public Health Service District requested that the sale of "baked or confectionary goods prepared in the kitchen of a private home" be allowed only from door-to-door sales; at farmer's markets, crafts fairs, or booths at special events; or on the internet and not through a regulated food establishment. The Apache County Public Health Service District stated that the rule created a "regulatory bias against permitted and inspected bakeries" and requested a definition of "retail sale" to exclude the sale of these goods from a "permitted food establishment." The Maricopa County Environmental Services Department also stated opposition to the sale of exempt baked or confectionary goods to regulated food establishments for retail sale and the provisions in the rule allowing such sale.	The Department does not believe that the intent of the statute is to limit the venues in which not-potentially hazardous baked or confectionary goods prepared in the kitchen of a private home may be sold. R9-8-102(C) specifically addresses this belief by making it clear that a regulated food establishment may purchase baked or confectionary goods that are exempt from the requirements of 9 A.A.C. 8, Article 1 and offer these goods for retail sale. The Department is using the dictionary definition of the term "retail sale" and does not see a need to define it. No change will be made to the rule.
An individual and the Maricopa County Environmental Services Department expressed concern about the labeling of not-potentially hazardous baked or confectionary goods, specifically the disclosure of allergens that may trigger life-threatening allergic reactions, and mentioned the possibility of cross-contamination of baked or confectionary goods prepared in the kitchen of a private home with allergens, even if the allergen is not an ingredient of the baked or confectionary goods.	The labeling requirements for exempt baked or confectionary goods are in rule and include a requirement for listing the ingredients. The label also provides notice to the public that these goods are not prepared in a regulated food establishment. Individuals who have allergies are more likely to read labels than the general public and may use this information in deciding whether or not to purchase the exempt baked or confectionary goods. No change will be made to the rule.
The Maricopa County Environmental Services Department expressed the following concerns about the accuracy of elements of the preliminary summary of the economic, small business, and consumer impact. The Maricopa County Environmental Services Department stated that "It is difficult to accept the cost/revenue projection for an industry that was not allowed in compliance with former state laws. In addition, there is not any mention of industry liability assumed under permitted establishments where home baked and confectionary goods are sold and distributed." The Maricopa County Environmental Services Department also stated that ADHS has not taken into account the consumer impact of this proposed rule on those businesses that currently operate in compliance with regulations."	The question of industry liability is outside the purview of the rules and is, therefore, not addressed in the economic, small business, and consumer impact statement (EIS) that was submitted to Council for review. The Department has addressed the county's concern in the EIS by adding wording to page 4 of the EIS stating that: "The amended rules may cause a minimal-to-moderate decrease in revenue to a county as a result of individuals who prepare not-potentially hazardous baked or confectionary goods that meet the requirements for exemption in statute and rule no longer obtaining unnecessary food establishment permits from the county." The EIS also states that "Persons who prepare baked or confectionary goods in a regulated food establishment may incur a decrease in revenue if potential customers buy home-baked or confectionary goods from unregulated individuals who have lower overhead expenses and may be able to undercut the prices charged by a regulated food establishment. Persons who rent kitchen space that meets the requirements in 9 A.A.C. 8, Article 1 to persons who prepare baked or confectionary goods may also incur a decrease in revenue if potential customers begin preparing the baked or confectionary goods in the kitchen of a private home. However, these impacts are caused by the exemption in statute, made in Laws 2011, Ch. 84, § 1, of not-potentially hazardous baked or confectionary goods prepared in the kitchen of a private home, rather than by the rule." No change will be made to the rule.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and, if not, the reasons why a general permit is not used:

The rule does not require a permit. A.R.S. § 36-136 provides for the licensing of food establishments. Although a county in Arizona may issue permits rather than licenses to food establishments, these permits are issued under a delegation agreement between the Department and the county in lieu of a license from the Department. Therefore, a general permit is not used.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and, if so, citation to the statutory authority to exceed the requirements of federal law:

No federal law is applicable to the subject of the rule. The U.S. Department of Health and Human Services, Food and Drug Administration periodically publishes editions of the Food Code, which is a reference document providing model requirements for safeguarding public health and ensuring food and drink is safe for human consumption. However, the authority to regulate food establishments comes from state statutes, and state regulatory agencies may adopt all or portions of specific editions of the Food Code, as well as other requirements not contained in the Food Code, to achieve state public health goals. This rulemaking does not involve the Section of the rules in 9 A.A.C. 8, Article 1 that adopts a version of the Food Code.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis comparing competitiveness was received by the Department.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 8. DEPARTMENT OF HEALTH SERVICES
FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION

ARTICLE 1. FOOD AND DRINK

Section
R9-8-101. Definitions
R9-8-102. Applicability

ARTICLE 1. FOOD AND DRINK

R9-8-101. Definitions

In addition to the terms defined in the material incorporated by reference in R9-8-107, which are designated by all capital letters, the following definitions apply in this Article, unless otherwise specified:

1. "Agency" means any board, commission, department, office, or other administrative unit of the federal government, the state, or a political subdivision of the state.
2. "Applicant" means the following PERSON requesting a LICENSE:
   a. If an individual, the individual who owns the FOOD ESTABLISHMENT;
   b. If a corporation, any officer of the corporation;
   c. If a limited liability company, the designated manager or, if no manager is designated, any member of the limited liability company;
   d. If a partnership, any two of the partners;
   e. If a joint venture, any two individuals who signed the joint venture agreement;
   f. If a trust, the trustee of the trust;
   g. If a religious or nonprofit organization, the individual in the senior leadership position within the organization.
   h. If a school district, the superintendent of the district;
   i. If an agency, the individual in the senior leadership position within the agency; or
   j. If a county, municipality, or other political subdivision of the state, the individual in the senior leadership position within the county, municipality, or political subdivision.
3. "Department" means the Arizona Department of Health Services.

4. "Developmental disability" means the same as in A.R.S. § 36-551.
~~4.~~5. "FC" means the United States Food and Drug Administration publication, Food Code: 1999 Recommendations of the United States Public Health Service, Food and Drug Administration (1999), as modified and incorporated by reference in R9-8-107.
~~5.~~6. "Incongruous" means inconsistent with the inspection reports of other inspectors or the REGULATORY AUTHORITY as a whole because significantly more or fewer violations of individual CRITICAL ITEMS are documented.
~~6.~~7. "Prepare" means to process commercially for human consumption by manufacturing, packaging, labeling, cooking, or assembling.
~~7.~~8. "Public health control" means a method to prevent transmission of foodborne illness to the CONSUMER.
~~8.~~9. "Remodel" means to change the PHYSICAL FACILITIES or PLUMBING FIXTURES in a FOOD ESTABLISHMENT'S FOOD preparation, storage, or cleaning areas through construction, replacement, or relocation, but does not include the replacement of old EQUIPMENT with new EQUIPMENT of the same type.
~~9.~~10. "Requester" means a PERSON who requests an approval from the REGULATORY AUTHORITY, but who is not an applicant or a LICENSE HOLDER.

R9-8-102. Applicability

A. Except as provided in subsection (B), this Article applies to any FOOD ESTABLISHMENT.

B. This Article does not apply to the following, which are not subject to routine inspection or other regulatory activities by a REGULATORY AUTHORITY:
1. The beneficial ~~Beneficial~~ use of wildlife meat authorized in A.R.S. § 17-240 and 12 A.A.C. 4, Article 1;
2. Group homes, as defined in A.R.S. Title 36, Chapter 5.1, Article 1;
3. Child care group homes, as defined in A.R.S. Title 36, Chapter 7.1, Article 4;
4. Residential group care facilities, as defined in 6 A.A.C. 5, Article 74, that have 20 or fewer clients;
5. Assisted living homes, as defined in 9 A.A.C. 10, Article 7;
6. Adult day health care services, as defined in 9 A.A.C. 10, Article 7, that have 15 or fewer clients;
7. Behavioral health service agencies, licensed under 9 A.A.C. 20, that provide residential or partial care services for 10 or fewer clients; ~~and~~
8. Hospice inpatient facilities, licensed under 9 A.A.C. 10, Article 8, that have 20 or fewer patients~~.~~;
9. Food or drink that is:
   a. Served at a noncommercial social event that takes place at a workplace, such as a potluck;
   b. Prepared at a cooking school if:
      i. The cooking school is conducted in the kitchen of an owner-occupied home,
      ii. Only one meal per day is prepared and served by students of the cooking school,
      iii. The meal prepared at the cooking school is served to not more than 15 students of the cooking school, and
      iv. The students of the cooking school are provided with written notice that the food is prepared in a kitchen that is not regulated or inspected by a REGULATORY AUTHORITY;
   c. Not potentially hazardous and prepared in a kitchen of a private home for occasional sale or distribution for noncommercial purposes;
   d. Prepared or served at an employee-conducted function that lasts less than four hours and is not regularly scheduled, such as an employee recognition, an employee fund-raising, or an employee social event;
   e. Offered at a child care facility and limited to commercially prepackaged food that is not potentially hazardous and whole fruits and vegetables that are washed and cut onsite for immediate consumption; or
   f. Offered at locations that sell only commercially prepackaged food or drink that is not potentially hazardous and that is displayed in an area of less than 10 linear feet; and
10. Baked or confectionary goods that are:
   a. Not potentially hazardous;
   b. Prepared in the kitchen of a private home for commercial purposes by or under the supervision of an individual who has obtained a food handler's card, if issued by the county in which the individual resides, and is registered with the Department, as required in A.R.S. § 36-136(H)(4)(g); and
   c. Labeled with:
      i. The name, address, and telephone number of the individual registered with the Department;
      ii. A list of the ingredients in the baked or confectionary goods;
      iii. A statement that the baked or confectionary goods are prepared in a private home; and
      iv. If applicable, a statement that the baked or confectionary goods are prepared in a facility for individuals with developmental disabilities.

C. A kitchen in a private home in which baked or confectionary goods are prepared that meets the requirements in A.R.S. § 36-136(H)(4)(g) and (H)(13) and subsection (B)(10) is an approved source of baked or confectionary goods for retail sale.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2698.) The Governor's Office authorized the notice to proceed through the rulemaking process on July 7, 2011.

[R11-204]

PREAMBLE

1. Articles Parts, or Sections Affected — **Rulemaking Action**

R9-22-1101	Amend
R9-22-1102	Amend
R9-22-1103	Repeal
R9-22-1104	Amend
R9-22-1105	Amend
R9-22-1106	Amend
R9-22-1108	Amend
R9-22-1109	Amend
R9-22-1110	Amend
R9-22-1111	Amend

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 36-2903.01

Implementing statute: A.R.S. §§ 36-2903.01, 36-2905.04, 36-2912, 36-2918

3. The effective date of the rules:

February 4, 2012

4. Citations to all related notices published in the *Register* to include the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 17 A.A.R. 1422, July 28, 2011

Notice of Proposed Rulemaking: 17 A.A.R. 1386, July 28, 2011

5. The agency's contact person who can answer questions about the rulemaking:

Name: Mariaelena Ugarte

Address: AHCCCS
Office of Administrative Legal Services
701 E. Jefferson St., Mail Drop 6200
Phoenix, AZ 85034

Telephone: (602) 417-4693

Fax: (602) 253-9115

E-mail: AHCCCSRules@azahcccs.gov

Web site: www.azahcccs.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

The Administration has initiated the following rulemaking regarding Civil Monetary Penalties as result of a five-year-rule review approved by the Governor's Regulatory Review Council on December 2, 2008.

The rule describes the process and circumstances under which AHCCCS imposes a penalty, assessment, or a penalty and assessment on a person, not only a provider or non-contracting provider. The rulemaking conforms the rule to statutory language which uses "person." AHCCCS anticipates that these rules will benefit all persons and AHCCCS by more clearly describing the process, circumstances, and timelines under which a penalty, assessment, or penalty and assessment are determined including more clearly describing the process used all persons.

It is anticipated that other "persons" such as members, fiscal agents, and small businesses, may be affected by this rulemaking if they meet the definition of "person" and are involved in a prohibited act. There are currently over 1M members in the AHCCCS program, 10 Acute Care Contractors, 9 ALTCS Care Contractors and their contracted or non-contracted providers in addition to those 54,758 AHCCCS Fee-For-Service (FFS) registered providers and non-contracting providers that provide FFS service that could be affected if they are involved in a prohibited act.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

No study was reviewed during this rulemaking and the agency does not anticipate reviewing any studies.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

AHCCCS anticipates that the probable costs and benefits to businesses affected, healthcare providers, will be approximately $1M. All providers are required to adhere to AHCCCS regulations and conduct their business in an ethical manner and will not have an impact when doing so.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

No additional changes have been made between the proposed rules and the final rules below. The Administration made the rules more clear, concise, and understandable by making grammatical, verb tense, punctuation, and structural changes throughout the rules.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

The Administration did not receive any comments regarding the rules.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rulemaking does not require a general permit because this rulemaking is not intended for facilities, activities or practices in a class that are substantially similar in nature and that are issued or granted by an agency to a qualified applicant to conduct identified operations or activities if the applicant meets the applicable requirements of the general permit, that requires less information than an individual or traditional permit, license or authorization and that does not require a public hearing.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

42 CFR 1000 through 42 CFR 1008 are applicable to the subject of the rule and the rule is not more stringent.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

A person did not submit an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

Not applicable

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

ARTICLE 11. CIVIL MONETARY PENALTIES AND ASSESSMENTS

Section

ARTICLE 11. CIVIL MONETARY PENALTIES AND ASSESSMENTS

R9-22-1101. Basis for Civil Monetary Penalties and Assessments for Fraudulent Claims; Definitions

A. Scope. This Article applies to ~~a provider or non-contracting provider who meets the conditions under this Article and who submits a claim under Medicaid (Title XIX of the Social Security Act), KidsCare (Title XXI of the Social Security Act), or the Health Care Group (A.R.S. § 36-2912)~~ prohibited acts as described under A.R.S. § 36-2918(A), and submissions of encounters to the Administration. The Administration considers a person who aids and abets a prohibited act affecting any of the AHCCCS programs or Health Care Group to be engaging in a prohibited act under A.R.S. § 36-2918(A).

B. Purpose. This Article describes the circumstances AHCCCS considers and the process that AHCCCS uses to determine the amount of a penalty, assessment, or penalty and assessment as required under A.R.S. § 36-2918. This Article includes the process and time-frames used by a ~~provider or non-contracting provider~~ person to request a State Fair Hearing.

C. Definitions. The following definitions apply to this Article:

1. "Assessment" means a monetary amount that does not exceed twice the dollar amount claimed by the ~~provider or non-contracting provider~~ person for each service.
2. "Claim" means a request for payment submitted by a ~~provider or non-contracted provider~~ person for payment for a service or line item of service, including a submission of an encounter.
3. "Day" means calendar day unless otherwise specified.
4. "File" means the date that AHCCCS receives a written acceptance, request for compromise, request for a counter proposal, or a request for a State Fair Hearing as established by a date stamp on the written document or other record of receipt.
5. "Penalty" means a monetary amount, based on the number of items of service claimed or reported, that does not exceed ~~two thousand dollars~~ $2,000 times the number of line items of service.
6. "Person" means an individual or entity as described under A.R.S. § 1-215.
~~6.~~7. "Reason to know" or "had reason to know" means that a ~~provider or non-contracting provider~~ person, acts in deliberate ignorance of the truth or falsity of, or with reckless disregard of the truth or falsity of information. No proof of specific intent to defraud is required.

R9-22-1102. Determining the Amount of a Penalty and an Assessment

A. AHCCCS shall determine the amount of a penalty and assessment according to A.R.S. § 36-2918(B) and (C), R9-22-1104, and R9-22-1105.

B. AHCCCS shall include in the amount of the penalty ~~the cost~~ and assessment the cost incurred by AHCCCS for conducting the following;

1. An investigation,
2. Audit, or
3. Inquiry.

R9-22-1103. ~~Determining the Amount of an Assessment~~ Repealed

~~**A.** AHCCCS shall determine the amount of an assessment according to A.R.S. § 36-2918(B) and (C), R9-22-1104, and R9-22-1105.~~

~~**B.** AHCCCS shall include in the amount of the assessment the cost incurred by AHCCCS for conducting the following:~~

~~1. An investigation,~~
~~2. Audit, or~~
~~3. Inquiry.~~

R9-22-1104. Mitigating Circumstances

AHCCCS shall consider any of the following to be mitigating circumstances when determining the amount of a penalty, assessment, or penalty and assessment.

1. Nature and circumstances of a claim. The following are mitigating circumstances:

a. All the services are of the same type,
b. All the dates of services occurred within six months or less,
c. The ~~services listed in subsection (1)(b)~~ number of claims submitted is ~~total~~ less than 25,
d. The nature and circumstances do not indicate a pattern of inappropriate claims for the services, and
e. The total amount claimed for the services is less than $1,000.

2. Degree of culpability. The degree of culpability of a ~~provider or non-contracting provider~~ person who presents or causes to present a claim is a mitigating circumstance if:
   a. Each service is the result of an unintentional and unrecognized error in the process that the ~~provider or non-contracting provider~~ person followed in presenting or in causing to present the service,
   b. Corrective steps were taken promptly by the ~~provider or non-contracting provider~~ person after the error was discovered, and
   c. The ~~provider or non-contracting provider~~ person had a fraud and abuse control plan that was operating effectively at the time each claim was presented or caused to be presented.
3. Financial condition. The financial condition of a ~~provider or non-contracting provider~~ person who presents or causes to present a claim is a mitigating circumstance if the imposition of a penalty, assessment, or penalty and assessment without reduction ~~jeopardizes the ability of the provider or non-contracting provider to continue as a health care provider~~ will render the provider incapable to continue providing services. AHCCCS shall consider the resources available to the ~~provider or non-contracting provider~~ person when determining the amount of the penalty, assessment, or penalty and assessment.
4. Other matters as justice may require. AHCCCS shall take into account other circumstances of a mitigating nature, if in the interest of justice, the circumstances require a reduction of the penalty, assessment, or penalty and assessment.

R9-22-1105. Aggravating Circumstances

AHCCCS shall consider any of the following to be aggravating circumstances when determining the amount of a penalty, assessment, or penalty and assessment.

1. Nature and circumstances of each claim. The nature and circumstances of each claim and the circumstances under which the claim is presented or caused to be presented are aggravating circumstances if:
   a. A ~~provider or non-contracting provider~~ person has forged, altered, recreated, or destroyed records;
   b. The ~~provider or non-contracting provider~~ person refuses to provide pertinent documentation to AHCCCS for a claim or refuses to cooperate with investigators ~~for other than constitutional reasons~~;
   c. The services are of several types;
   d. All the dates of services did not occur within six months or less;
   e. The ~~services rendered in subsection (1)(d)~~ number of claims submitted is ~~are~~ greater than 25;
   f. The nature and circumstances indicate a pattern of inappropriate claims for the services; and
   g. The total amount claimed for the services is $5,000 or greater.
2. Degree of culpability. The degree of culpability of a ~~provider or non-contracting provider~~ person who presents or causes to present each claim is an aggravating circumstance if:
   a. The ~~provider or non-contracting provider~~ person knows or had reason to know that each service was not provided as claimed,
   b. The ~~provider or non-contracting provider~~ person knows or had reason to know that no payment could be made because the ~~provider or non-contracting provider~~ person had been excluded from reimbursement by AHCCCS, or
   c. The ~~provider or non-contracting provider~~ person knows or had reason to know that the payment would violate the terms of an agreement between the ~~provider or non-contracting provider~~ person and AHCCCS system.
3. Prior offenses. The prior offenses of a ~~provider or non-contracting provider~~ person who presents or causes to present each claim are an aggravating circumstance if:
   a. At any time before the submittal of the claim the ~~provider or non-contracting provider~~ person was held criminally or civilly liable for any act; or
   b. The ~~provider or non-contracting provider~~ person had received an administrative sanction in connection with:
      i. A Medicaid program,
      ii. A Medicare program, or
      iii. Any other public or private program of reimbursement for medical services.
4. Effect on patient care. The adverse effect on patient care that resulted, or could have resulted, from the failure to provide medically necessary care by a person in connection with a claim ~~of a provider or non-contracting provider who presents or causes to present a claim to provide medically necessary care~~.
5. Other matters as justice may require. AHCCCS shall take into account other circumstances of an aggravating nature, if in the interest of justice, the circumstances require an increase of the penalty, assessment, or penalty and assessment.

R9-22-1106. Notice of Intent

If AHCCCS imposes a penalty, assessment, or a penalty and assessment, AHCCCS shall hand deliver or send by certified mail return receipt requested or Federal Express to the ~~provider or non-contracting provider~~ person, a written Notice of Intent to impose a penalty, assessment, or a penalty and assessment. The Notice of Intent shall include:

1. The statutory basis for the penalty, assessment, or the penalty and assessment;
2. Identification of the state or federal regulation and state or federal law that AHCCCS alleges has been violated;
3. The factual basis for AHCCCS' determination that the penalty, assessment, or the penalty and assessment should be imposed;
4. The amount of the penalty, assessment, or penalty and assessment;
5. The process for the ~~provider or non-contracting provider~~ person to accept or request a compromise of the penalty, assessment, or penalty and assessment; and
6. The process for requesting a State Fair Hearing.

R9-22-1108. Request for a Compromise

A. To request a compromise, the ~~provider or non-contracting provider~~ person shall file a written request with AHCCCS within 30 days from the date of receipt of the Notice of Intent. The written request for compromise shall contain the ~~provider or non-contracting provider's~~ person's reasons for the reduction or modification of the penalty, assessment, or penalty and assessment.

B. Within 30 days from the date of receipt of the request for compromise from the ~~provider or non-contracting provider~~ person, AHCCCS shall send a Notice of Compromise Decision ~~and accept, deny, or offer~~ that accepts, denies, or offers a counter proposal to the ~~provider or non-contracting provider's~~ person's request for compromise. If AHCCCS offers a counter proposal the amount of the counter proposal shall represent the penalty, assessment, or penalty and assessment.

1. If AHCCCS does not withdraw the Notice of Intent under R9-22-1112 or denies the request for compromise the original penalty, assessment, or penalty and assessment is upheld.
2. To dispute the Compromise Decision, the ~~provider or non-contracting provider~~ person shall file a request for a State Fair Hearing under R9-22-1110 within 30 days from the date of receipt of the Notice of Compromise Decision.

R9-22-1109. Failure to Respond to the Notice of Intent

If a ~~provider or non-contracting provider~~ person fails to respond timely to the Notice of Intent, AHCCCS shall uphold the original penalty, assessment, or penalty and assessment.

R9-22-1110. Request for State Fair Hearing

A. To request a State Fair Hearing regarding a dispute concerning a penalty, assessment, or penalty and assessment, the ~~provider or non-contracting provider~~ person shall file a written request for a State Fair Hearing with AHCCCS within 60 days from the date of the receipt of the Notice of Intent under R9-22-1106 or within 30 days from the date of receipt of the Notice of Compromise Decision under R9-22-1108, if applicable.

B. AHCCCS shall mail a Notice of Hearing under A.R.S. § 41-1092.05 if AHCCCS receives a timely request for a State Fair Hearing from the ~~provider or non-contracting provider~~ person.

C. AHCCCS shall mail a Director's Decision to the ~~provider or non-contracting provider~~ person no later than 30 days after the date the Administrative Law Judge sends the decision of the Office of Administrative Hearings (OAH) to AHCCCS.

D. AHCCCS shall accept a written request for withdrawal of a hearing request if the written request for withdrawal is received from the ~~provider or non-contracting provider~~ person before AHCCCS mails a Notice of Hearing under A.R.S. § 41-1092 et seq. If AHCCCS mailed a Notice of Hearing under A.R.S. § 41-1092 et seq., a ~~provider or non-contracting provider~~ person may withdraw the hearing request only by sending a written request for withdrawal to OAH.

R9-22-1111. Issues and Burden of Proof

A. Preponderance of evidence. In any State Fair Hearing conducted under R9-22-1110, AHCCCS shall prove by a preponderance of the evidence that a ~~provider or non-contracting provider~~ person presented or caused to be presented each claim in violation of this Article and any aggravating circumstances under R9-22-1105. A ~~provider or non-contracting provider~~ person shall bear the burden of producing and proving by a preponderance of the evidence any circumstance that would justify reducing the amount of the penalty, assessment, or penalty and assessment.

B. Statistical sampling.

1. In meeting the burden of proof described in subsection (A), AHCCCS may introduce the results of a statistical sampling study as evidence of the number and amount of claims that were presented or caused to be presented by the ~~provider or non-contracting provider~~ person. A statistical sampling study constitutes prima facie evidence of the number and amount of claims if ~~based upon an appropriate sampling and~~ computed by valid statistical methods.
2. The burden of proof shall shift to the ~~provider or non-contracting provider~~ person to produce evidence reasonably calculated to rebut the findings of the statistical sampling study once AHCCCS has made a prima facie case as described in subsection (B)(1). AHCCCS shall be given the opportunity to rebut this evidence.

NOTICE OF FINAL RULEMAKING

TITLE 10. LAW

CHAPTER 3. DEPARTMENT OF LAW
CIVIL RIGHTS DIVISION

Editor's Note: The following Notice of Final Rulemaking was exempt from Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 2698.)

[R11-206]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R10-3-401	Amend
R10-3-402	Amend
R10-3-403	Amend
R10-3-404	Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 41-192(B)(2), 41-1492.06

Implementing statutes: A.R.S. §§ 41-1492 through 41-1492.12

3. The effective date of the rules:

February 7, 2012

4. A list of all previous notices appearing in the Register addressing the proposed rules:

Notice of Rulemaking Docket Opening: 17 A.A.R. 1952, September 30, 2011

Notice of Proposed Rulemaking: 17 A.A.R. 1906, September 30, 2011

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:	Ann Hobart, Civil Rights Division, Litigation Section Chief Counsel
Address:	1275 W. Washington St. Phoenix, AZ 85007-2926
Telephone:	(602) 542-8608
Fax:	(602) 542-8899
E-mail:	ann.hobart@azag.gov

6. An explanation of the rules, including the agency's reasons for initiating the rules:

In enacting the Arizonans with Disabilities Act (AzDA), the Legislature intended to provide "a uniform accessibility code" for Arizona that is "consistent" with the Americans with Disabilities Act (ADA) and its implementing regulations. Laws 1992, Ch. 224, § 1(B)(4) and (C). It thus mandated that compliance with Titles II and III of the ADA and its implementing regulations be deemed compliance with the AzDA. A.R.S. § 41-1492.06(B). The Legislature granted the Attorney General authority to adopt rules to carry out the AzDA. A.R.S. § 41-1492.06(A). It required, however, that such rules not exceed the regulations, guidelines and standards issued by the U.S. Department of Transportation and the U.S. Department of Justice relating to Titles II and III of the ADA. A.R.S. § 41-1492.06(B). It also required the Attorney General to periodically review and amend its rules to achieve consistency with regulations promulgated pursuant to the ADA. A.R.S. § 41-1492.06(C). The Attorney General has general authority to "adopt rules for the orderly conduct of the business" of the Department of Law pursuant to A.R.S. § 41-192(B)(2).

On September 15, 2010, a final rule amending the U.S. Department of Justice's regulations relating to Titles II and III of the ADA was published in the *Federal Register*. The amended regulations, which include changes to 28 CFR 35 and 36 and the 2010 Standards for Accessible Design (2010 Standards), which are comprised of 28 CFR 35.151, 36.401 through 36.406, and appendices B and D to 36 CFR 1191, went into effect on March 15, 2011. Compliance with the 2010 Standards was permitted as of September 15, 2010, and will be required as of March 15, 2012.

In addition, despite two efforts to amend A.A.C. R10-3-402 in 1996 and 1997, the Arizona Attorney General has never adopted the ADA regulations promulgated by the U.S. Department of Transportation. *See* 3 A.A.R. 1258, May 9, 1997, 2 A.A.R. 4865, December 6, 1996. Because the relevant federal rules were last amended in 2006, it is now necessary for the Attorney General to adopt certain parts of them and incorporate them by reference into the state rules.

To achieve consistency with the revised federal ADA regulations as required by A.R.S. § 41-1492.06(C), the Attorney General must amend A.A.C. R10-3-401, R10-3-402, R10-3-403, and R10-3-404 to reflect the amendments to 28 CFR 35 and 36 and 36 CFR 1191, to incorporate the 2010 Standards, and to incorporate the relevant Department of Transportation regulations.

7. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rules.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

The proposed rules will impact public entities, places of public accommodation, commercial facilities, and private owners and operators of specified public transportation. However, because the proposed amendments simply achieve consistency between state and federal law and create no new legal obligations, the Office of the Attorney General anticipates minimal economic impact as a result of the rule changes. It is also anticipated that the proposed rule changes will provide enhanced clarity for the business community because state and federal regulations regarding accessibility issues will be consistent.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The Office of the Attorney General discovered an inconsistency between Item 12 and Item 13 of the Notice of Proposed Rulemaking in which 49 CFR 37.3 was inadvertently included in the text of R10-3-402. To correct this error and effect the Office of the Attorney General's intention as stated in Item 12 of the Notice of Proposed Rulemaking, 49 CFR 37.3 has been deleted from the final rules. 49 CFR 38.3, which incorporates 49 CFR 37.3 by reference, also has been deleted.

R10-3-402 has been amended to distinguish between Department of Justice and Department of Transportation regulations incorporated into the rule.

11. A summary of the comments made regarding the rules and the agency response to them:

The Office of the Attorney General did not receive any comments regarding the rules during the period designated for written comments or at the public hearing that took place on November 1, 2011.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

Appendices B and D to 36 CFR 1191 (2009), as modified by Appendix F to 36 CFR 1191 (2009), 49 CFR 37.5, 37.7(a), 37.9(a) through (c), 37.21(a)(2) through (3), 37.23(b) and (d), 37.25(a), 37.27-37.29, 37.37(a) through (f) and (h), 37.45, 37.49, 37.51(a) through (b), 37.55 through 37.57, 37.101 through 37.107, 37.161, 37.165 through 37.173, 37.187 through 37.189, 37.197, 37.201 through 37.211 and Appendix A to Part 37 (2010), and 49 CFR 38.1, the first sentence of 38.2, 38.4, 38.21 through 38.161, 38.171(a) through (b), 38.173 through 38.175, 38.179, and the Figures to Part 38 (2010) are incorporated in R10-3-402. Appendices B and D to 36 CFR 1191 (2009) and the provisions of 28 CFR 35.130(b)(4), 35.133, 35.135, 35.136, 35.137, 35.150, 35.151 and 35.163 (2011) are incorporated in R10-3-403. Appendices B and D to 36 CFR 1191 (2009) and the provisions of 28 CFR 36.101 through 36.104, 36.201 through 36.206, 36.208, 36.211, 36.301 through 36.311, 36.401 through 36.406, and 36.507 (2011) are incorporated in R10-3-404.

14. Were these rules previously made as emergency rules?

No

15. The full text of the rules follows:

TITLE 10. LAW

CHAPTER 3. DEPARTMENT OF LAW
CIVIL RIGHTS DIVISION

ARTICLE 4. THE ARIZONANS WITH DISABILITIES ACT

Section
R10-3-401. Definitions

ARTICLE 4. THE ARIZONANS WITH DISABILITIES ACT

R10-3-401. Definitions

The following terms used in this Article or in the materials incorporated by reference in this Article have the following meaning:

1. "2010 Standards" means for:
   a. Public entities, appendices B and D to 36 CFR 1191 (2009) and 28 CFR 35.151 (2011).
   b. Places of public accommodation and commercial facilities, appendices B and D to 36 CFR 1191 (2009) and 28 CFR 36.401 through 36.406 (2011).

~~1.~~2. "Act" or "the Act" No change

~~2. "ADAAG" means Appendix A to 28 CFR 36, referred to as the "Americans with Disabilities Act Accessibility Guidelines."~~

3. "Assistant Attorney General" No change
4. "Attorney General" No change
5. "National" No change
6. "Respondent" No change

R10-3-402. Nondiscrimination on the Basis of Disability by Specified Public Transportation

Private entities that are ~~Owners~~ owners and operators of specified public transportation shall comply with the provisions of ~~36 CFR 1191 and accompanying appendix, adopted September 6, 1991 and no further amendments, relating to specified public transportation services by a private entity, which are adopted, incorporated by reference and~~ Appendices B and D to 36 CFR 1191 (2009), as modified by Appendix F to 36 CFR 1191 (2009), and no further amendments, which are adopted and incorporated herein by reference. Copies of the incorporated material are on file with the Office of the Arizona Attorney General Civil Rights Division~~, the Office of the Arizona Secretary of State,~~ and the United States Department of Justice Civil Rights Division, ~~P.O. Box 66738, Washington, D.C. 20035.~~ Disability Rights Section - NYA, 950 Pennsylvania Avenue, NW, Washington, D.C. 20530. Private entities that are owners and operators of specified public transportation also shall comply with the provisions of 49 CFR 37.5, 37.7(a), 37.9(a) through (c), 37.21(a)(2) through (3), 37.23(b) and (d), 37.25(a), 37.27 through 37.29, 37.37(a) through (f) and (h), 37.45, 37.49, 37.51(a) through (b), 37.55 through 37.57, 37.101 through 37.107, 37.161, 37.165 through 37.173, 37.187 through 37.189, 37.197, 37.201 through 37.211 and Appendix A to Part 37 (2010), and 49 CFR 38.1, the first sentence of 38.2, 38.4, 38.21 through 38.161, 38.171(a) through (b), 38.173 through 38.175, 38.179, and the Figures to Part 38 (2010), and no further amendments, which are adopted and incorporated herein by reference. Copies of the incorporated material are on file with the Office of the Arizona Attorney General Civil Rights Division and the United States Department of Transportation, 1200 New Jersey Avenue, SE, Washington, D.C. 20590.

R10-3-403. Nondiscrimination on the Basis of Disability by Public Entities

~~A.~~ Public entities shall comply with ~~the provisions of 28 CFR 35.130(b)(4), 35.133, 35.135, 35.150, 35.151, 35.163, and Appendix A to 28 CFR 36, adopted July 26, 1991, and no further amendments, which are adopted, incorporated by reference and~~ the 2010 Standards and the provisions of 28 CFR 35.130(b)(4), 35.133, 35.135, 35.136, 35.137, 35.150, and 35.163 (2011), and no further amendments, which are adopted and incorporated herein by reference. Copies of the incorporated material are on file with the Office of the Attorney General Civil Rights Division~~, the Office of the Secretary of State,~~ and the United States Department of Justice Civil Rights Division, ~~P.O. Box 66738, Washington, D.C. 20035.~~ Disability Rights Section - NYA, 950 Pennsylvania Avenue, NW, Washington, D.C. 20530.

~~B. 28 CFR 35.150(c), as incorporated by this Section, is amended as follows:~~

~~1. A public entity shall comply with the obligations of this Section relating to provision of curb ramps or other sloped areas where existing public pedestrian walkways cross curbs at locations serving state and local government offices and facilities, transportation, places of public accommodation, employers, and the residences of individuals with disabilities no later than January 26, 1997, but in any event as expeditiously as possible.~~

~~2. A public entity shall comply with the obligations of this Section relating to provision of curb ramps or other sloped areas where existing public pedestrian walkways cross curbs at areas not subject to subsection (B)(1) no later than January 26, 1997, but in any event as expeditiously as possible.~~

~~3. If a public entity has responsibility or authority over streets, roads, or walkways, its transition plan shall include a specific schedule for the installation of curb ramps or other sloped areas where pedestrian walkways cross curbs that complies with the requirements of subsections (B)(1) and(2).~~

R10-3-404. Nondiscrimination on the Basis of Disability by Places of Public Accommodation and in Commercial Facilities

Places of public accommodations and commercial facilities shall comply with the ~~provisions of 28 CFR 36 and accompanying~~

~~Appendix A (referred to as the "Americans with Disabilities Act Accessibility Guidelines" or "ADAAG"), adopted July 26, 1991, and no further amendments, with the exception of 28 CFR §§ 36.207, 36.209, 36.210 through 36.214, 36.306 through 36.307, 36.501 through 36.506, 36.508, and 36.601 through 36.608, which are adopted, incorporated by reference and~~ 2010 Standards and the provisions of 28 CFR 36.101 through 36.104, 36.201 through 36.206, 36.208, 36.211, 36.301 through 36.311, and 36.507 (2011), and no further amendments, which are adopted and incorporated herein by reference. Copies of the incorporated material are on file with the Office of the Attorney General Civil Rights Division~~, the Office of the Secretary of State,~~ and the United States Department of Justice Civil Rights Division, ~~P.O. Box 66738, Washington, D.C. 20035.~~ Disability Rights Section - NYA, 950 Pennsylvania Avenue, NW, Washington, D.C. 20530.